UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,872	03/30/2004	Dominique Charmot	RLY 04031.102	5573

58415 7590 03/05/2009

SENNIGER POWERS LLP (ILPS)
100 NORTH BROADWAY
17TH FLOOR
ST. LOUIS, MO 63102

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
03/05/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/813,872	CHARMOT ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,16,17,20-24,31,32,45-65 and 67-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,16,17,20-24,31,32,45-65 and 67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 10/14/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 10, 16, 17, 20-24, 31, 32, 45-65, and 67-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an oral pharmaceutical compositions comprising a core-shell particles where the shell is crosslinked, does not reasonably provide enablement for a shell component comprising a polymer having permeability for potassium ion that is higher than the permeability for a competing cation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) The breadth of the claims; The claims are drawn to a pharmaceutical dosage form comprising core-shell particles and any excipients, wherein the core is any compound capable of acting as a cation exchange resin and the shell comprising any crosslinked polymer that has a higher permeability for potassium ion over competing cations, where the shell has a particular thickness. The core and shell polymers are only identified by their function and as such any compound meeting these functional limitations would meet the limitations of the claims. This

would result in possibly thousands of compounds that meet these limitations, compounds that are not encompassed by the specification in a meaningful way. (B) The nature of the invention; the rejected claims are drawn to pharmaceutical dosage forms comprising core-shell particles, and methods of using said dosage forms for the removal of ions from the body. (C) The state of the prior art; The current state of the art as shown in the Notenbomer (EP 0 730 494) patent shows that pharmaceutical dosage forms that remove ions, specifically potassium and sodium, from the body are known in the art. However the reference is silent to whether the polymer of the shell has increase permeability to competing cations other than sodium, potassium or ammonium. The polymer is more permeable based on the valance of the ions and not the molecular structure such as screening sodium from potassium or vice versa. (D) The level of one of ordinary skill; The level of skill in the art would be an individual with at least post doctoral work in polymer chemistry and pharmacology. (E) The level of predictability in the art; Given a specific polymeric formula, with properly identified functional groups, and integer values a polymer can be accurately predicted to its full polymerization. However by only providing a list of presumed properties for a polymer, the predictability would decline. In such cases it is proper for the USPTO to required evidence that such an unprecedented accomplishment has been accomplished *In re Feren*, 163 USPQ 609. No such evidence has been provided. The failure of skilled artisan scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genetech vs. Novo Nordisk*, 42 USPQ 2nd 1001, 1006. (F) The amount of direction provided by the inventor; The entire specification is directed to phosphate binding, with only mention of potassium binding in a list of possible other ions. Nothing in the specification indicates which polymers would be useful for specifically choosing a polymer that

is more permeable to potassium ions over any other competing ion. The specification indicates that crosslinked polymers that are made from the polymerization ethylenic or vinylic groups would be useful in a phosphate binding shell, however provides no particulate guidance as to which of these many thousands of polymers would be useful as a potassium permeable shell that would also differentiate and select out other competing cations. Of the tables and extensive list of polymers, none are pointed out to be particularly useful as being more permeable to potassium ions while also being non-permeable to competing ions. (G) The existence of working examples; The working examples in the specification are drawn to forming core particles and polymer shells, however these core-shell particles are designed for and tested for phosphate binding. In fact the phosphate binding occurs in ex vivo experiments. The core-shell particles are never administered to a human in need of ion removal. Moreover the working examples never disclose how to make, or screen for or identify a polymer has an increased permeability for potassium ions over competing cations. The working examples do provide an extensive table of phosphate permeable shell polymers, but has no disclosures whatsoever of a shell component that would be more permeable to potassium rather than competing cations. (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. The claims are an invitation to experiment in order to find a specific polymer that 1) is permeable to potassium ions the art allows passage through the polymer to the cation exchange resin core, and 2) would somehow keep out competing cations from the core. An artisan would first have to screen for all known crosslinked or cross-linkable polymers that were permeable to potassium ions. These polymers would number in the hundreds of thousands. Next the person of ordinary skill would have to find from those polymers which not only had permeability for potassium

ions, but those that had an increased permeability for potassium over competing ions. These polymers would number in the thousands, and must be tested for safety and efficacy. These polymers must also not disintegrate in the intestinal system as well. The specification provides ample examples for binding and removing phosphate ions, and provides no guidance or working examples for binding and removing potassium ions. The artisan of ordinary skill is invited to experiment in order to find such a polymer and without proper guidance for the specification this experimentation would be undue. As such the specification has not met the written description requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recites that the pharmaceutical formulation of claim 3 comprising a core-shell particles that do not disintegrate in the intestine in the form of a solution. However a solution cannot comprise non dissolved particles. By definition, all components of a solution are fully dissolved. A liquid formulation comprising the non-disintegrating particles of the invention would be a dispersion, not a solution. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 16, 17, 20, 21, 23, 31, 32, 46-50, 54, 57-63 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Notenbomer (EP 0 730 494 hereafter '494). The claims are drawn to a pharmaceutical formulation comprising core-shell particle and excipients where the core is a cation exchange resin and the shell is a crosslinked synthetic polymer.

The '494 patent teaches a particle formulation comprising a core and a coating where the core comprises a cation exchange resin and the coating does not disintegrate during passage through the intestinal tract of humans and where the membrane is more permeable to monovalent cations rather than bi-or higher cations (page 1, lin. 49-55). The particles can be mixed with sodium chloride as an excipient and administered orally as a foodstuff (page 2, lin. 54-60). The particles are safe means of absorbing cations from the digestive tract, encapsulating the ions and removing them as waste from the body (page 2, lines 8-12). The cation exchange materials come from a wide range of sources and can include sulphonated crosslinked polystyrenes, polycarboxylates, polymaleinates, polyacrylates and polyphosphates (page 2, lin. 20-34). The coating comprises polyethyleneimine as well as known detergents (page 2, lin. 42-45; example 2). The coating is crosslinked by toluene-2,4-diisocynate (example 2). The particles can be further coated with cellulose acetate a well known enteric polymer (example 1). The reference is silent to the specific monomers of the instant claims. The particles are microcapsules that range in size from 0.01-10 mm in size, with specific ranges of approximately 290 microns (page 2, lin. 41-42; Example 1). The particles can be formulated in various pharmaceutical forms including tablets, pills and capsules (page 3, lines 15-18).

Regarding the condition the human patient is suffering for, the fact that the shell is applied via a coating method, it is the position of the Examiner that such limitations are merely a future intended use for the dosage form, and do not obviate over the prior art. As discussed above the prior art combination discloses the same oral pharmaceutical formulation comprising the same components. The prior art discloses a structurally identical pharmaceutical formulation comprising the same components, as such the condition suffered by the patient is irrelevant to the formulation itself. Inclusion of the condition adds an implicit method of administration step to the product claim, meaning the limitations are product-by-process claims.

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10, 16, 17, 20-24, 31, 32, 46-50, 54-63, and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Notenbomer (EP 0 730 494 hereafter '494) in view of Cohen et al (USPN 6,558,665 hereafter '665). The claims are drawn to an oral formulation comprising core-shell particles wherein the core comprises a cation-exchange resin and the coating is hydrophobic.

The '494 patent discloses a particle formulation comprising a core and a coating where the core comprises a cation exchange resin and the coating does not disintegrate during passage through the intestinal tract of humans and where the membrane is more permeable to monovalent cations rather than bi-or higher cations (page 1, lin. 49-55). The particles can be mixed with sodium chloride as an excipient and administered orally as a foodstuff (page 2, lin. 54-60). The particles are safe means of absorbing cations from the digestive tract, encapsulating the ions and removing them as waste from the body (page 2, lines 8-12). The cation exchange materials come from a wide range of sources and can include sulphonated crosslinked polystyrenes, polycarboxylates, polymaleinates, polyacrylates and polyphosphates (page 2, lin. 20-34). The coatings range polyethyleneimine to known detergents (page 2, lin. 42-45; example 2). The particles can be further coated with cellulose acetate a well known enteric polymer (example 1).

The reference is silent to the specific monomers of the instant claims. The particles are microcapsules that range in size from 0.01-10 mm in size, with specific ranges of approximately 290 microns (page 2, lin. 41-42; Example 1). The particles can be formulated in various pharmaceutical forms including tablets, pills and capsules (page 3, lines 15-18). The thickness of the coating can be adjusted during the coating process, whether through fluidized bed coating or via interfacial polymerization. Coating thickness manipulation can be seen in the '665 patent.

The '665 patent discloses uniform coating surrounding particles (abstract). The coating is uniform from 10-20 microns thicken and can comprise a crosslinked polyethylene glycol (col. 7, lin. 15-20), along with other surfactants such as Poloxamer (col. 7, lin. 40-45). The coatings can be applied using interfacial polymerization (col. 7, lin. 58-60). Polystyrene particles measuring from 200-300 microns are coated with crosslinked polyethylene glycol at a thickness of 20 microns (example). That is a 0.1:1 ratio of components in order to achieve such as thickness and diameter. It would have been obvious to coat the particles of the '494 patent in a similar fashion of the '665 patent since they both use the same method to apply uniform coatings.

Regarding the percentages of retained potassium ions, it is the position of the Examiner that such percentages would be obvious in view of the prior art. It is the position of the Examiner that these retention percentages are merely functional limitations that are inherent to the components of the instant claims. The '494 and '665 patents discloses coated particles comprising polymeric cores comprising the same components as those recited in the claims, specifically crosslinked styrene or sulphonic polymers, coated by crosslinked synthetic polymers with polymerized ethylenic monomers. The coatings are applied in the same thickness and for the same purpose of removing cations from the digestive system. Specific cations include

potassium. The combined disclosures meet the general conditions of the instant claims, and would inherently meet the functional limitations of the claims. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the condition the human patient is suffering for, it is the position of the Examiner that such limitations are merely a future intended use for the dosage form, and do not obviate over the prior art. As discussed above the prior art combination discloses the same oral pharmaceutical formulation comprising the same components. The prior art discloses a structurally identical pharmaceutical formulation comprising the same components, as such the condition suffered by the patient is irrelevant to the formulation itself. Inclusion of the condition adds an implicit method of administration step to the product claim, meaning the limitations are product-by-process claims.

The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324,

326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

With these things in mind it would have obvious to coat the particles of the '494 patent in a uniform thickness as disclosed in the '665 patent. The patens disclose similar method of coating and comprise similar components, and as such it would have been obvious to coat the particles to a uniform thickness of 10-20 microns as disclosed in the '665 patent. One of ordinary skill in the art would have been motivated to combine the teachings disclosure and suggestions of the prior art as such with an expected result of a stable coated cation exchange resin useful in removing cations from the intestinal tract of a human.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Notenbomer (EP 0 730 494 hereafter '494) in view of Chong et al (USPN 4,380,590 hereafter '590). The claims are drawn to a method of treating hyperkalemia in a human patient in need of treatment with a pharmaceutical formulation comprising core-shell particles with a specific configuration.

As disclosed as the '494 patent discloses a pharmaceutical product useful in removing specific ions from the intestinal tract of humans. The ions removed depend on the cation exchange resin in the core. The ions removed can be sodium, potassium or ammonium. The

reference is silent to specific disorders treated with this formulation; however it would be obvious to treat any conditions where ion reduction would be a treatment option.

The '590 patent discloses a cation exchange resin emulsion comprising a crosslinked copolymer component selected from the group consisting of styrene, vinyl, acrylic or methacrylic monomers (col. 5, lin. 15-52). Among the many uses for the cation exchange resin is a treatment for hyperkalemia (col. 9, lin. 35-55).

It would have been obvious to one of ordinary skill in the art to treat hyperkalemia with a cation exchange resin as disclosed in the prior art in order to sufficiently remove excess potassium ions from the body. Under the suggestion of the '590 patent to use acid cation ion exchange resins to treat hyperkalemia, the artisan of ordinary skill would have been motivated to apply the composition of the '494patent in order to remove excess potassium ions from the body effectively treating hyperkalemia in a human patient in need of treatment.

Claims 1, 51-53, 62, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Notenbomer (EP 0 730 494 hereafter '494) in view of Shimzu et al (USPN 5,824,339 hereafter '339) and Macek et al (USPN 3,499,960 hereafter '960). The claims are drawn to a pharmaceutical formulation comprising core shell particles where the core is a cation exchange resin and the shell is a specific polymer.

As discussed above the combination of the '494 patent discloses a pharmaceutical composition comprising core-shell particles with a desired shell and core. The reference is silent to the specific shell components of the instant claims. These shell components are well known in the art and would have been obvious additions. The reference discloses the use of crosslinked

ethylic monomers in the shell, and suggests any useful polymer that can be made permeable to the desired valent cation is useful. These coating components can be found in the '339 and '960 patents.

The '339 patent discloses a core-shell particle formulation comprising a shell component comprising crosslinked polyvinylpyrrolidone, and a core comprising carboxyl functional groups (col. 8, lin. 14-25; col. 6, lin. 36-51). The core-shell particles further contain excipients and stabilizers to make them more palatable for oral administration (examples). The '960 patent discloses a palatable ion exchange formulation comprising a coating of crosslinked acrylic polymers (abstract).

It would have been obvious to include these shell components into the formulation of the '494 patent in order to provide sufficient permeability of potassium ions into the cation exchange core. It would have been obvious to combine the teachings and suggestions with an expected result of a palatable oral formulation useful in the treatment of a variety of ion related disorders.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 10, 16, 17, 20-24, 31, 32, 45-65, and 67-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 4, 14, 15, 18-22, 29, 30, 34, 36, 40, and 51-76 of copending Application No. 10/814,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims recite pharmaceutical formulations comprising core-shell formulation comprising potassium-binding polymers that are crosslinked. The formulations both have shells with thicknesses up to 50 microns. These claims would act as obviating art over each other.

2. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1, 10, 16, 17, 20-24, 31, 32, 45-65, and 67-69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618